

II. General Comments

Claims 66 to 70 and 72 have been amended to clarify the present invention. Support for each individual amendment is found in the present specification as filed. Claims 66, 68, 70, and 72 have been amended to replace "y" with --β-- where indicated. This was clearly a typographical error in the Preliminary Amendment. Claims 66, 68, 70, and 72 have been amended to clarify antecedent basis for the term "tautomeric forms thereof." Claims 67 to 70 have been amended to replace "the desired coloration" with --a desired coloration--.

In summary, no amendment was made for any prior art reason and no amendment introduces new matter. Thus, no estoppel has been introduced by any of the present amendments.

III. Objection under Rule 1.75(c)

The Office objected to claims 66, 68, 70, and 72 due to the presence of the symbol "y" for the reason set forth on page 2 of the present Office Action. These claims have been amended to replace "y" with --β-- where indicated to render this objection moot. Thus, Applicants respectfully request that this objection be withdrawn.

IV. Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 66, 68, 70, and 72 have been rejected under 35 U.S.C. § 112, second paragraph for the reasons found on pages 2 and 3 of the present Office Action.

Applicants respectfully submit that the amendments to each claim have rendered this rejection moot. Claims 66, 68, 70, and 72 have been amended to clarify antecedent basis for the term "tautomeric forms thereof." Claims 68 to 70 have been amended to replace "the desired coloration" with --a desired coloration--. Along these lines, claim 67, even though not rejected, has been amended to replace "desired coloration" with --a desired coloration--. Accordingly, Applicants respectfully request that this rejection be withdrawn with respect to each rejected claim.

V. Rejections under 35 U.S.C. § 103(a)

Yamahatsu

Claims 32 to 64, 66 to 68, and 74 have been rejected under 35 U.S.C. § 103(a) over Yamahatsu (EP 716,846) for the reasons found on pages 3 and 4 of the present Office Action. According to *M.P.E.P.* § 2142, the Office has the initial burden to establish a *prima facie* case of obviousness by pointing to three well-known, basic criteria, which will not be recited here. Applicants respectfully traverse this rejection, at least because there would have been no motivation to modify the teachings of Yamahatsu based upon the prior art of record and common knowledge. Thus, a *prima facie* case of obviousness has not been established.

Yamahatsu teaches hair dyeing compositions containing the oxidation bases p-phenylenediamine and p-aminophenol, the couplers m-aminophenol and m-

phenylenediamine, and the enzyme uricase and its donor as the oxidizing system. As admitted by the Office (p. 4 of the Office Action), Yamahatsu does not exemplify a composition containing "at least one first oxidation base chosen from para-phenylenediamine compounds other than para-phenylenediamine" as recited, for example, in present claims 32 and 67. However, the Office takes the position that Yamahatsu teaches the equivalence between para-phenylenediamine and para-phenylenediamine compounds other than para-phenylenediamine, such as 2,5-diamine-toluene, thus making it obvious to substitute one for the other.

The recitation by Yamahatsu of para-phenylenediamine and 2,5-diamine-toluene oxidation bases in the same list does not necessarily teach an equivalence for the purpose of the present invention. There are almost 40 compounds listed as "oxidation dyes" by Yamahatsu at p. 3, lines 6-15. One skilled in the art would have had to pick and choose the correct ingredients, *i.e.*, 2 specific types of oxidation bases and 1 specific type of coupler, to have even a chance of reaching the claimed invention of claims 32 to 64, 66 to 68, and 74.

Yamahatsu carries out 5 experiments relating to the improved stability of the enzyme, uricase, in its compositions. According to Yamahatsu, uricase stability is tested by using oxygen as an acceptor and a substrate as a donor (p. 2, lines 18-21). Experiment 1 of Yamahatsu regards pH and uricase stability; Experiment 2 regards reducing agents and uricase stability; Experiment 3 regards pH adjusting agents and

uricase stability; Experiment 4 regards water concentration and uricase stability; and Experiment 5 regards stability of uricase activity. Because each of these experiments uses para-phenylenediamine, these experiments cannot and do not create a desirability to modify the para-phenylenediamine of Yamahatsu's compositions to obtain the presently claimed composition.

Moreover, Yamahatsu exemplifies 9 other compositions, all of which contain para-phenylenediamine. Because each of these examples uses para-phenylenediamine, these examples cannot and do not create a desirability to modify the para-phenylenediamine of Yamahatsu's compositions to obtain the presently claimed composition.

Further, the examples and experiments of Yamahatsu show a preference away from oxidation bases more complicated than para-phenylenediamine. Specifically, Yamahatsu shows 39 compositions in the examples and experiments. Every one of those 39 compositions contains para-phenylenediamine. Clearly, Yamahatsu teaches away from using a para-phenylenediamine oxidation base other than para-phenylenediamine itself.

As a result, at the time Applicants' invention was made, there would have existed no desire to modify the teachings of Yamahatsu. This lack of desirability to modify means the Office has failed to establish a *prima facie* case of obviousness. Thus, this rejection should be withdrawn with respect to each claim from 32 to 64, 66 to 68, and

74.

Yamahatsu in view of Husemeyer

Claims 32 to 64, 66 to 68, 73, and 74 have been rejected under 35 U.S.C. § 103(a) over Yamahatsu in view of Husemeyer (United States Patent No. 4,840,639) for the reasons on pages 4 to 6 of the Office Action. Applicants respectfully traverse this rejection, at least because there was no motivation to combine and/or modify the teachings of Yamahatsu and Husemeyer based upon the prior art of record and common knowledge. Thus, a *prima facie* case of obviousness has not been established.

Yamahatsu is discussed in the previous section. As relevant here, Yamahatsu is deficient for two (2) reasons. First, as admitted by the Office (at p. 4 of Office Action), Yamahatsu does not exemplify a composition comprising "at least one first oxidation base chosen from para-phenylenediamine compounds other than para-phenylenediamine" as presently recited in claims 32, 66, 67, and 68. Second, as admitted by the Office (p. 5 of Office Action), Yamahatsu does not teach or suggest the 2- β -hydroxyethyl-para-phenylenediamine di-hydrochloride oxidation base recited in claim 73. As a result, the teachings of Yamahatsu must be combined with the teachings of another reference to remedy these two (2) deficiencies.

To remedy these deficiencies, the Office combines the teachings of Yamahatsu with the teachings of Husemeyer. Husemeyer discloses compositions comprising

1-hydroxyalkyl-2,5-diaminobenzenes (col. 1, lines 44-59) that embrace the 2- β -hydroxyethyl-para-phenylene diamine di-hydrochloride oxidation base of claim 73. Husemeyer, however, fails to recite a composition with two (2) oxidation bases, let alone the particular types of oxidation bases recited, for example, in claim 32. Moreover, Husemeyer fails to recite "at least one enzyme" or "at least one donor" in its list of oxidants but particularly prefers hydrogen peroxide (see col. 2, lines 57-65).

The Office argues that it would have been obvious to substitute para-phenylenediamine and/or 2,5-diamine-toluene, from the Examples of Yamahatsu, with the 1-hydroxyalkyl-2,5-diaminobenzenes of Husemeyer. According to the Office, this combination and modification is desirable for two (2) reasons: (1) Yamahatsu is concerned with storage stability of its compositions; and (2) Husemeyer teaches that its compositions comprising 1-hydroxyalkyl-2,5-diaminobenzenes have improved properties, like shelf-life, toxicology, and improved color.

Despite these two (2) reasons, however, the Office has failed to present "clear and particular" evidence that Yamahatsu and Husemeyer should be combined. As for the Office's first reason, the Office over-generalizes the teachings of Yamahatsu. Yamahatsu concerns only the stability of *uricase* in its compositions. Yamahatsu states this in certain terms: "The main object of the present invention is to improve stability of uricase in a hair dye composition" Page 2, lines 18-21. Yamahatsu also teaches that one achieves uricase stability by using oxygen as an acceptor and a substrate as a

donor (p. 2, lines 18-21). This is shown by each of the Examples of Yamahatsu, which considered the effects of pH (Experiment 1), reducing agents (Experiment 2), pH adjusting agents (Experiment 3), water concentration (Experiment 4), and uricase activity (Experiment 5) on uricase stability. Yamahatsu also fails to suggest a concern with oxidation bases, in general, and uricase stability. As a result, Yamahatsu must not be read to concern the stability of other ingredients, like Husemeyer's 1-hydroxyalkyl-2,5-diaminobenzenes.

As for the Office's second reason, *i.e.*, that Husemeyer's 1-hydroxyalkyl-2,5-diaminobenzenes exhibit improved properties, like shelf-life, toxicology, and improved color, the Office gives each of these properties too much weight. Husemeyer states that its 1-hydroxyalkyl-2,5-diaminobenzenes have a "long shelf life" (col. 1, line 68-col. 2, line 1). Long is a relative term, and Husemeyer never mentions the standard for comparison. Despite that, Husemeyer clearly refers to the 1-hydroxyalkyl-2,5-diaminobenzenes, not the other ingredients of the composition containing the 1-hydroxyalkyl-2,5-diaminobenzenes.

As for the alleged improved toxicology, Applicants respectfully submit that Husemeyer's statements about the toxicologic aspects (col. 3, lines 22-27) are indecipherable. What is the "progress" Husemeyer mentions (col. 3, line 22)? Where is Husemeyer's evidence in support of these proclamations? These statements teach nothing to one of ordinary skill in the art.

As for the alleged improved color, the Office cites a *prophetic*, not actual, comparison (col. 3, lines 46-50). Husemeyer lists coloring "possibilities" (col. 3, line 29) in the future tense. This and the use of future tense throughout col. 3, lines 28 to 50, shows that Husemeyer's claim: "A deepening of color may be observed in an analogous manner" (col. 3, lines 46-47) is a possible result, not an actual result.

Despite being prophetic, this prediction regards one oxidation base, one coupler, and most likely an oxidant such as hydrogen peroxide, but definitely not an oxidant such as an enzyme/donor, which Husemeyer fails to even acknowledge. This must be compared to the claimed invention as a whole. For example, claim 32 recites a composition comprising "at least one first oxidation base," "at least one coupler," "at least one second oxidation base," "at least one enzyme," and "at least one donor." Three ingredients of this claim Husemeyer's prophetic prediction fails to consider. As such, Husemeyer's prediction is not relevant to the present claimed invention as a whole.

As a result, there existed no desire to combine the teachings of Yamahatsu and Husemeyer. A lack of desirability means the Office has failed to establish a *prima facie* case of obviousness. This rejection should be withdrawn for this reason alone with respect to each claim from 32 to 64, 66 to 68, 73, and 74.

As another reason that this rejection should be withdrawn, there would have been no motivation to modify the compositions of Yamahatsu for the reasons stated in

the previous section of this reply. As noted above, Yamahatsu shows a preference away from more complicated oxidation bases than para-phenylenediamine, because Yamahatsu exemplifies 39 compositions, all of which contain para-phenylenediamine. As such, Yamahatsu teaches away from using a para-phenylenediamine oxidation base other than para-phenylenediamine itself.

As a result, there would have existed no desire to modify the teachings of Yamahatsu, regardless of the teachings of Husemeyer. This lack of desirability to modify means the Office has failed to establish a *prima facie* case of obviousness. This rejection should be withdrawn with respect to each rejected claim from 32 to 64, 66 to 68, 73, and 74.

Cotteret in view of Tsujino

Claims 32 to 72 and 74 have been rejected under 35 U.S.C. § 103(a) in view of Cotteret (United States Patent No. 5,514,188) in view of Tsujino (United States Patent No. 4,461,925) the reasons found on pages 6 to 8 of the Office Action. Applicants respectfully traverse this rejection, at least because there was no motivation for one of ordinary skill in the art to combine the teachings of these documents. Thus, a *prima facie* case of obviousness has not been established.

Cotteret recites a composition comprising "at least one oxidation dye precursor" chosen from p-aminophenols, "at least one oxidation dye precursor" chosen from p-phenylenediamines, a "coupling agent" 2-methyl-5-aminophenol, and "oxidizing agent"

(col. 4, lines 27-44). Cotteret's "oxidizing agent" preferably includes hydrogen peroxide, but Cotteret also discloses urea peroxide, persalts, and alkali metal bromates (col. 5, lines 7-10). Cotteret mentions no other type of "oxidizing agent" (see col. 5, lines 7-10).

Thus, Cotteret is deficient, because, as admitted by the Office (p. 7 of Office Action), Cotteret does not teach or suggest a composition containing "at least one enzyme" and "at least one donor" as recited in claims 32 and 66 to 72. Specifically, Cotteret fails to render obvious a composition as recited in claims 32 and 66 to 72, because Cotteret fails to teach or suggest or provide basis for a reasonable expectation of success for any a composition with "at least one enzyme" and "at least one donor." Claims 33 to 65, and 74 depend directly or indirectly from claim 32. As a result, the teachings of Cotteret must be combined with the teachings of another reference.

To remedy these deficiencies, the Office combines the teachings of Cotteret with Tsujino. Tsujino teaches hair dye compositions containing oxidation dyes and enzyme/donor oxidizing systems. Tsujino does not exemplify a composition comprising an oxidation base and a coupler chosen from "at least one coupler" as presently recited, for example, in independent claim 32. Moreover, Tsujino neither teaches nor suggests the presently claimed combination of "at least one first oxidation base," "at least one second oxidation base," "at least one coupler," "at least one enzyme," and "at least one donor."

Collectively, therefore, the combined teachings of these documents alone fail to set forth a desire to combine the teachings of Cotteret with those of Tsujino. According to *M.P.E.P.* § 2143, just because two references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *See also In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Also, according to the same section, the teaching or suggestion to make the claimed combination must be found in the references, and not based on the present disclosure. *See also In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Importantly, with respect to this motivation, the Federal Circuit has clarified that the burden is on the Office to present "clear and particular" evidence showing motivation to combine. *See In re Dembiczak*, 50 USPQ.2d 1614 (Fed. Cir. 1999).

Here, the Office has failed to present "clear and particular" evidence that the teachings of Cotteret and Tsujino should be combined. The Office takes the position that it would have been obvious to one of ordinary skill in art to substitute the hydrogen peroxide oxidants of with an enzyme/donor system, because Tsujino teaches that enzyme/donor systems give superior results in dyeing, e.g., decreased skin irritation and damage to hair and skin (see Office Action at p. 8). In Applicants' view, however, the Office gives too much weight to Tsujino's generalized proclamations.

In examples 1-12 and 1-13, Tsujino uses hydrogen peroxide as its oxidizing agent. Tsujino states that using hydrogen peroxide gave "excellent" dyeing properties

but "poor" finish of hair (see col. 5, lines 39-42). Tsujino also states that "[a]ccording to the present invention, a good finish of hair can be obtained while retaining *almost the same dyeing effect* as that by using hydrogen peroxide as the oxidizing agent." Col. 5, lines 43-46 (emphasis added). In other words, Tsujino appears to be saying that using enzyme/donor systems as oxidants may not give as good a color as peroxide oxidant systems, e.g., see Examples 1-1, 1-2, 1-4, where color was not as dark, but where the finish was improved versus peroxide systems. Based on this statement, one of ordinary skill in the art would hardly have predicted an improvement in the dyeing properties of Cotteret's composition by substituting the hydrogen peroxide with the enzyme/donor pairs of Tsujino.

Furthermore, Tsujino and Cotteret collectively fail to recognize the significance of the presently claimed combination of ingredients. Although Tsujino notes that its oxidants are less irritating, nowhere does Cotteret suggest a desirability for a new oxidant or a need for a less irritating oxidant. In addition, nowhere does Cotteret provide a basis for predicting what would happen when one uses the enzyme/donor pairs of Tsujino as an oxidant. Cotteret focuses upon a combination of a coupler and oxidation bases.

On the other hand, Tsujino focuses upon finding a "satisfactory mild oxidant" (col. 1, lines 35-35) to replace harsh oxidants (col. 1, line 27). Tsujino remains not even

tangentially concerned with a coupler in combination with oxidation bases as set forth in Cotteret: nowhere does Tsujino suggest a desirability for combinations of "at least one first oxidation base," "at least one second oxidation base," "at least one coupler chosen from meta-aminophenols . . . " as presently recited, for example, in claim 32. In fact, nowhere does Tsujino provide a basis for predicting what would happen when one uses a combination of these particular ingredients with "at least one enzyme" and "at least one donor" as presently recited, for example, in claim 32. Moreover, as just noted, there would be no improvement expected with regard to the purpose of Cotteret, and hence no motivation to switch oxidants from hydrogen peroxide to the enzyme/donor pairs of Tsujino.

As a result, there is no reason why one of ordinary skill would have combined the teachings of Cotteret and Tsujino. This lack of desirability to combine or modify means the Office has failed to establish a *prima facie* case of obviousness. Thus, this rejection should be withdrawn with respect to each claim from 32 to 72 and 74.

VI. Obviousness-Type Double Patenting Rejection

The Office has rejected claims 32 to 74 under the judicially created doctrine of obviousness type double patenting as being unpatentable over the U.S. Application No. 09/319,165 for the reasons found on pages 8 and 9 of the present Office Action. Applicants respectfully request to hold this provisional rejection in abeyance until an indication of allowable subject matter is made in this or the '165 application.

CONCLUSION


In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of the pending claims and the timely allowance of the pending claims.

If the Office has any questions about this case, please contact Sean A. Passino at 202.408.6065.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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